REMARKS/ARGUMENTS

Claims 19-29 and 33-40 are in the application. Claims 1 and 3-18 have been canceled and rejections relating thereto have been rendered moot. Claims 38-40 have been amended to correct typographical errors. Pending claims 19-29 and 33-40 have all been rejected, and these rejections are respectfully traversed for the following reasons.

I. Claims 19-29

The Examiner rejected claims 19-32 under 35 U.S.C. §103(a) as being unpatentable over Lawecki et al. in view of Logothetis (U.S. Patent No. 4,521,237). (N.B. Claims 30-32 were previously cancelled and only claims 19-29 are currently in the application.) The Examiner asserted that

> Lawecki discloses a method for producing glass syringe barrels (column 3, lines 35-43) including a step of transferring the glass syringe barrels to an enclosure of class 100 environment in order to maintain a predetermined cleanliness level of the syringe barrels from the time the syringe barrels are fabricated to the time the syringe barrels are placed in sealed containers for shipment (abstract). The method of Lawecki meets all of applicant[s'] claimed subject matter except for the detailed process of forming a glass syringe.
>
> However, Logothetis discloses a method for forming a glass syringe barrel (1) on a forming device (column 3, lines 40-43) wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to form a flange (column 3, lines 57-62; Figures 1 & 2); the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (column

> 5, lines 8-14; Figure 5); the syringe barrel is then heated to an annealing temperature (column 4, lines 24-27).
>
> Therefore, it would have been obvious to an ordinary [person] skilled in the art at the time the invention was made to have modified the method of Lawecki by having provided a forming device for forming the glass syringe barrels, as taught by Logothetis, in order to produce glass syringe barrels prior to transferring the glass syringe barrels [to] the enclosure of class 100 environment in order to maintain a predetermined cleanliness level of the glass syringe barrels during the processing of the glass syringe barrels.

The Examiner's assertions are respectfully traversed.

Lawecki et al. is specifically directed to forming an article, such as by molding, with sufficient heat to render the molded article substantially free from contaminants (column 1, lines 53-58; column 3, lines 35-41). If insufficient heat is provided during molding, internal surfaces of the molding isolation module 12 can be periodically sterilized, such as with sterilizing gas or vapor (column 3, lines 43-48; column 8, lines 30-45). To prevent contaminants from settling on the clean surfaces of the molded articles, continuous laminar air flow is provided to the molding isolation module 12. (Column 4, lines 23-25). The molded articles are transferred from the molding isolation module 12 to the packaging isolation module 14 which also includes continuous laminar air flow. (Column 2, lines 18-20; column 6, lines 49-51). It is clear from the teachings of Lawecki et al. that Lawecki et al. seeks to form a product free of contaminants, either by providing sufficient heat at the time of formation or by using sterilization, and to

provide sufficient air flow thereafter to prevent contaminants from settling on the clean surfaces of the formed products.

With reference to Logothetis, Logothetis specifically requires sterilizing in addition to annealing a syringe: "...the syringe is completed by being **annealed, sterilized**, and filled with the desired medicine or dosage." (Column 4, lines 26-28) (Emphasis applied).

To establish a prima facie showing of obviousness, there must be some motivation or suggestion to combine Logothetis and Lawecki et al. as suggested by the Examiner. MPEP §2143.01. There is no motivation or suggestion to combine Logothetis with Lawecki et al. as suggested by the Examiner. As discussed above, Lawecki et al. calls for forming a "clean" syringe barrel and continuously maintaining the barrel's cleanliness thereafter. There is no suggestion in Lawecki et al. to have a syringe barrel be formed outside of a clean environment and then introduced thereinto. Consequently, there is no motivation or suggestion to modify Lawecki et al. to introduce syringe barrels formed in accordance with Logothetis outside of a clean environment and then introducing the syringe barrels into a clean environment.

In addition, the hypothetical combination suggested by the Examiner would improperly change the principle of operation of Lawecki et al. MPEP §2143.01 ("If the proposed

modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.") The proposed combination seeks to alter the Lawecki et al. principle of forming articles "clean" and maintaining that cleanliness. It is respectfully submitted that for the foregoing reasons, the hypothetical combination of Lawecki et al. and Logothetis does not provide a prima facie showing of obviousness.

Assuming arguendo that even if a prima facie showing of obviousness can be made, all of the limitations of claim 19 are not taught or suggested by the hypothetical combination. MPEP §2143.03. The Examiner has suggested a hypothetical combination of the Logothetis method of forming a syringe barrel and then transferring the formed barrel to a clean environment such as that disclosed by Lawecki et al. Based on the teachings of Lawecki et al., the clean enclosure is used to maintain the cleanliness of a clean product, while the teachings of Logethetis require that a product must be sterilized to be made clean. Consequently, the hypothetical method requires the steps of annealing, sterilizing and then transferring the syringe barrel to the clean environment. In contrast, claim 19 includes the steps of forming, annealing and then "immediately transferring said syringe barrels to at least one housing assembly for maintaining a predetermined cleanliness level". With the invention of claim 19, the glass syringe barrels are transferred to a housing assembly for maintaining cleanliness after annealing without any

intervening sterilization. The forming and annealing steps can be performed outside the housing for maintaining cleanliness. There is no suggestion or motivation in Lawecki et al. and Logothetis to anneal a syringe barrel and then transfer it to a clean environment without sterilization. It is respectfully submitted that claim 19, along with dependent claims 20-29, are patentable over Lawecki et al. and Logothetis, each taken alone or in combination.

II. Claims 33-36 and 37-40

Claims 33, 34, 37 and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lawecki et al. in view of AAPA (Applicant Admitted Prior Art). The Examiner asserted that Lawecki "meets all of applicant's claimed subject matter but lacks the specific teaching of the way the plastic syringe being filled." The Examiner relied on Applicants' specification at page 31, line 19 - page 32, line 6 for allegedly disclosing that a syringe barrel can be filled by a known method, in overcoming the deficiency of Lawecki et al.

Claims 33 and 37 each include the steps of "delivering a tip cap to said environmentally controlled area" and "air cleaning said tip cap in said environmentally controlled area". The Examiner referred to the former step in formulating the rejection, but not to the latter step. There is no disclosure or suggestion in Lawecki et al. to air clean tip caps which are delivered into the clean environment. With reference to Lawecki et al., any additional articles to be assembled

with the syringe barrels are to be formed in secondary molding isolation modules, such as second molding isolation module 212. (Column 8, lines 1-18). Within the principles of Lawecki et al. discussed above, any additional molded articles are to be either prepared with sufficient heat to be contaminant-free or be prepared under some form of sterilization medium. Tip seals are referred to in only one place in Lawecki et al., namely column 8, line 25. As stated therein, "intermediate module 250 may be used for applying a lubricant, such as silicone oil, to the manufactured articles, for example, the inner barrel surfaces...or...tip seals (not shown)." It is clear from the statement that tip seals are intended to be considered manufactured articles in Lawecki et al. Accordingly, Lawecki et al. discloses manufacturing tip seals within its system - not introducing tip seals from an external source. Consistent with the disclosure of Lawecki et al., the tip seals are to be formed clean within the system and maintained clean. There is no disclosure or suggestion in Lawecki et al. to provide tip caps and to air clean those tip caps as set forth in claims 33 and 37. The AAPA relied upon by the Examiner relates only to filling syringes, not to preparing individual components therefor. As such, the AAPA does not overcome the deficiency of Lawecki et al. It is respectfully submitted that claims 33 and 37, along with dependent claims 34-36 and 38-40, respectively, are patentable over Lawecki et al. and the AAPA, each taken alone or in combination.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,

Ludomir A. Budzyn
Registration No.: 40,540
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700